



US009545399B2

(12) **United States Patent**
Tu et al.(10) **Patent No.:** **US 9,545,399 B2**(45) **Date of Patent:** ***Jan. 17, 2017**(54) **METHYLPHENIDATE EXTENDED RELEASE CHEWABLE TABLET**(2013.01); **A61K 9/284** (2013.01); **A61K 9/2846** (2013.01); **A61K 9/5026** (2013.01)(71) Applicant: **Tris Pharma, Inc.**, Monmouth Junction, NJ (US)(58) **Field of Classification Search**CPC **A61K 9/2072**; **A61K 9/2077**USPC **424/465, 489**

See application file for complete search history.

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(21) Appl. No.: **15/200,625**(22) Filed: **Jul. 1, 2016**(65) **Prior Publication Data**

US 2016/0310479 A1 Oct. 27, 2016

Related U.S. Application Data

(63) Continuation of application No. 15/009,480, filed on Jan. 28, 2016, which is a continuation of application No. 14/872,226, filed on Oct. 1, 2015, now Pat. No. 9,295,642, which is a continuation of application No. 14/624,998, filed on Feb. 18, 2015, now Pat. No. 9,180,100, which is a continuation of application No. 14/300,580, filed on Jun. 10, 2014, now Pat. No. 8,999,386, which is a continuation of application No. PCT/US2013/054930, filed on Aug. 14, 2013, application No. 15/200,625, filed on Jul. 1, 2016, which is a continuation of application No. 15/009,468, filed on Jan. 28, 2016, which is a continuation of application No. 14/872,226, which is a continuation of application No. 14/624,998, which is a continuation of application No. 14/300,580, which is a continuation of application No. PCT/US2013/054930.

(60) Provisional application No. 61/774,783, filed on Mar. 8, 2013, provisional application No. 61/683,513, filed on Aug. 15, 2012.

(51) **Int. Cl.****A61K 9/20** (2006.01)**A61K 9/22** (2006.01)**A61K 31/4458** (2006.01)**A61K 9/00** (2006.01)**A61K 9/28** (2006.01)**A61K 9/50** (2006.01)(52) **U.S. Cl.**CPC **A61K 31/4458** (2013.01); **A61K 9/0056** (2013.01); **A61K 9/20** (2013.01); **A61K 9/2027** (2013.01); **A61K 9/2054** (2013.01); **A61K 9/2072** (2013.01); **A61K 9/2077** (2013.01); **A61K 9/2081** (2013.01); **A61K 9/2086**

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(57)

ABSTRACT

An oral methylphenidate extended release tablet is described, which can be scored and still retain its extended release profile. The tablet contains a combination of an uncoated methylphenidate-ion exchange resin complex, a barrier coated methylphenidate-ion exchange resin complex-matrix, and an uncomplexed methylphenidate active component. Following administration of a single dose of the extended release methylphenidate chewable tablet, a therapeutically effective amount of methylphenidate is reached in less than about 20 minutes and the composition provides a twelve-hour extended release profile.